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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,064	10/05/2005	Oliver Schadt	MERCK-3067	6539
23599 7590 05/07/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER JARRELL, NOBLE E	
			ART UNIT 1609	PAPER NUMBER
			MAIL DATE 05/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/552,064		SCHADT ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Noble Jarrell		1609	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 1-17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/05/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION*****Status of Application***

1. The Response to Election/ Restriction dated April 3, 2007 is acknowledged. Claims 1-7, 10, and 14 are rejoined with claims 8-13 and 15-17. Group III and compound 8 are recognized.

Applicants contend that search burden was not shown in original restriction and that the full scope of the invention can be searched without a serious burden. However, since there are so many possible substituents on variables  $R^1$ ,  $R^2$ ,  $R^3$ , and  $R^4$ , the full scope presents a serious burden. Take for example, the group "het". This group can be an "aromatic or in particular heterocyclic radical which in unsubstituted or substituted by A." (page 35, lines 5-6 of the specification). From this broad definition, "het" is any heterocyclic ring. Applicant goes on to state that "het" can also be dimethylamino or ethyl-methyl-amino moiety. Based on the definition of "het" taken from the specification, a search burden exists, and "het" can be either a heterocyclic ring or a heteroalkyl group. Since "het" is part of variables  $R^1$ - $R^4$ , a serious search burden does exist. Take, for example, Jiaang et al. (US20070093492, published April 26, 2007) have structures on pages 2-3 of the specification with rings that could mean "het." Some examples are pyrrolidine, benzopyrrolidine, thiazoline fused with piperadine, 1,3,4-triazole fused with piperadine, and benzene fused with piperadine.

Therefore, the restriction is deemed proper and MADE FINAL

***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 04/05/2003. It is noted, however, that applicant has not filed a certified copy of the 103 15 569.4 application as required by 35 U.S.C. 119(b).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

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4. Claims 11-13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 11-13 and 16 provides for the use of compounds of formula I, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 11-13 and 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

6. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Under variables  $R^3$  and  $R^4$ , there are three indeterminate substituents. They are  $(CH_2)_n\text{---}000R^5$ ,  $(CH_2)_nN(R^5)C(R^5)H000R^5$ , and  $(CH_2)_nN(R^5)CH_2CH_2N(R^5)CH_2\text{---}000R^5$ . As best the examiner can tell, these groups are typos and should be  $(CH_2)_nOCOR^5$ ,  $(CH_2)_nN(R^5)C(R^5)COOR^5$ , and  $(CH_2)_nN(R^5)CH_2CH_2N(R^5)COOR^5$ , respectively.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

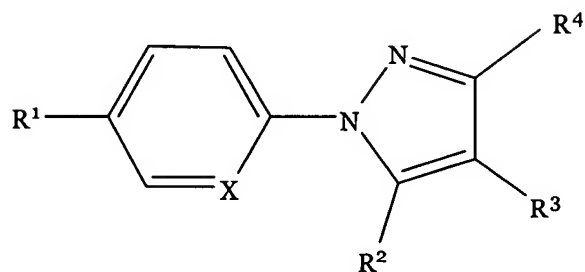
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-2, 11-14 are provisionally rejected on the ground of nonstatutory obviousness-type

double patenting as being unpatentable over claim 1-2, 11-14 of copending Application No. 10/551905.

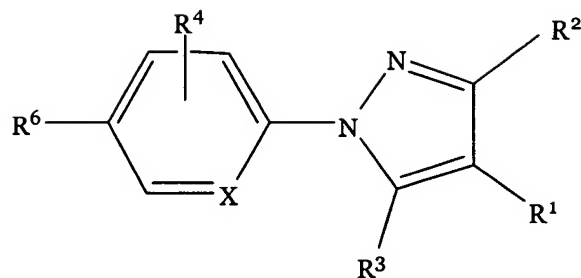
Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications embrace each other. Figure 1, shown below, shows formula I in each of the applications.

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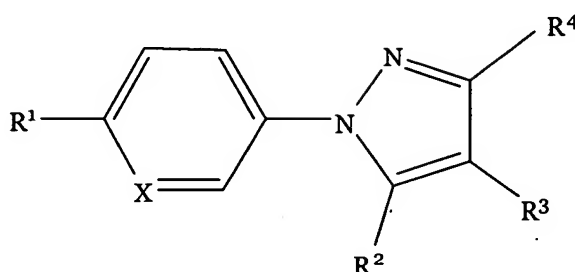
X=CH or N

Formula I in the instant application



X=CH

Formula I in 10/551905



X=CH or N

Formula I in 10/552065

Figure 1: Formula I in each of the applications

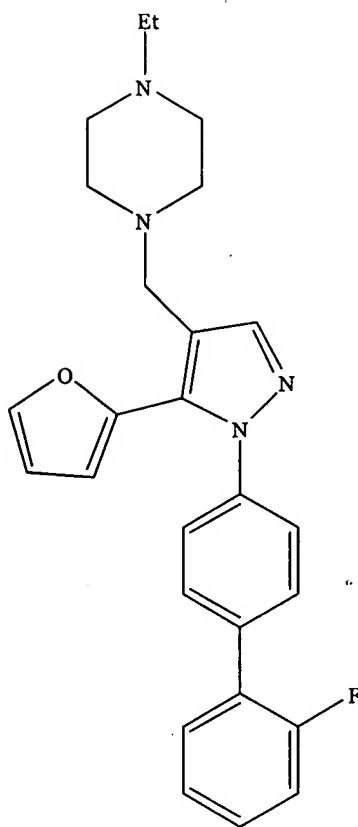
As is shown in figure 1, variable  $R^1$  in the instant application is equivalent to variable  $R^6$  in 10/551905. Following the same logic,  $R^2$  (instant) equals  $R^3$  (10/551905),  $R^3$  equals  $R^1$ , and  $R^4$  equals  $R^2$ . Although the definitions of these variables are not equivalent in each application, formulae I of each application embrace each other. The following table shows the meaning of some of the variable in the applications.

Instant Application		10/551905	
<u>Variable</u>	<u>Meaning</u>	<u>Variable</u>	<u>Meaning</u>
$R^1$	H, A, Hal, $(CH_2)_n$ Het, etc.	$R^6$	$(CH_2)_n$ Het
$R^2$	$(CH_2)_n$ Het	$R^3$	$(CH_2)_n$ Het
$R^3, R^4$	H, $(CH_2)_n$ Het	$R^1, R^2$	$(CH_2)_n$ Het ( $R^1$ ), H, A,

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			Hal (R <sup>2</sup> )
R <sup>5</sup>	H or A	R'	H or A
A	C <sub>1-10</sub> alkyl or alkoxy, C <sub>2-10</sub> alkenyl or alkoxyalkyl	A	C <sub>1-10</sub> alkyl or alkoxy, C <sub>2-10</sub> alkenyl or alkoxyalkyl
Het	A saturated, unsaturated or aromatic mono- or bicyclic heterocyclic or linear or branched organic radical	Het	A saturated, unsaturated or aromatic mono- or bicyclic heterocyclic or linear or branched organic radical
Ar	Phenyl (unsubstituted or substituted)	Ar	Phenyl (unsubstituted or substituted)

In addition, the elected species in the instant application, 1-ethyl-4-((1-(2'-fluorobiphenyl-4-yl)-5-(furan-2-yl)-1H-pyrazol-4-yl)methyl)piperazine, shown below is in both applications, and is a species of claim 1 in both applications.



Even though the scope of the two applications is not identical, there is a case of obvious type double patenting the same species is embraced by formula I of both applications. The above structure is structure 8 on page 29 in the specification of the instant application and structure 8 on page 26 of the specification in 10/551905. This is only one example of a species that is embraced by both formulae, and there may be other species that do the same.

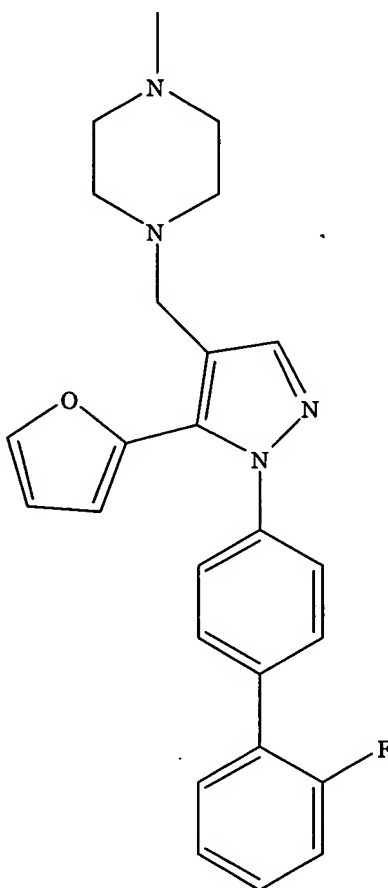
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 12-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2-3 of copending Application No. 10/552065. Although the conflicting claims are not identical, they are not patentably distinct from each other because formulae I of each application embrace each other, even though they are not of the same scope. Claims 12-13 of the instant use formula I as 5-HT receptor antagonist and a s 5-HT<sub>2A</sub> receptor antagonist, respectively.



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Claims 2-3 of 10/552065 are worded the same way as claims 12-13 of the instant application. The only difference between formula I in each application is the placement of variable X, as seen in figure 1. In the instant application, X is *ortho* to the link to the pyrazole ring and in 10/552065, variable X is *meta* to the linkage. One compound that is produced in 10/552065 and is anticipated by formulae I in both applications is 1-((1-(2'-fluorobiphenyl-4-yl)-5-(furan-2-yl)-1H-pyrazol-4-yl)methyl)-4-methylpiperazine, which is shown below. This compound is compound 103 (page 41 of the specification) of 10/552065.



Since this compound is an acceptable species of formulae I in both applications, there is a case of obvious type double patenting.

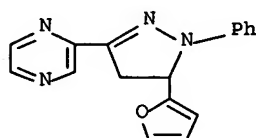
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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*Allowable Subject Matter*

10. No claims are allowed. However, the compounds 1-703 that fall within the elected group are free of the prior art of record. The only documents with the elected species are applicants' own work.

11. The following is a statement of reasons for the indication of allowable subject matter: The closest prior art of record is the structure shown below, which was entered into STN November 16, 1984.



This structure does not anticipate the elected group or species because the six-membered ring with two nitrogens is not piperazine, but pyrazine.

*Conclusions*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on Monday-Friday from 7:30 to 6:00. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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NJ

VICKIE KIM  
PRIMARY EXAMINER

